DECLARATION OF MICHAEL E. ELIA, M.D.

1. I, MICHAEL E. ELIA, M.D., have been retained by King Pharmaceuticals, Inc. ("King") to opine on the effect on clinical practice of the omission of bioavailability information from the labeling for generic versions of SKELAXIN®, a muscle relaxant drug product.

I. EXPERT QUALIFICATIONS

2. I have spent over ten years practicing as an orthopaedic surgeon. In this time, I have treated hundreds of cases involving skeletal muscle pain. Based on my experience, which is discussed in more detail below, I am knowledgeable in the field of skeletal pain management.

3. I am a physician and the Director in the Department of Orthopaedic Surgery at Lawrence Hospital, Bronxville, New York, and an Attending Orthopaedic Surgeon at St. Luke's/Roosevelt Hospital, New York, New York.

4. I am a licensed physician in New York State, and I have extensive experience with administering skeletal muscle relaxants, including SKELAXIN®.

5. Following receipt of my Medical Degree in 1982 from Georgetown University School of Medicine, I did a General Surgery Internship at St. Elizabeth Hospital, in Boston, Massachusetts (1982-1983) and an Orthopaedic Residency at St. Luke's/Roosevelt Hospital Center in New York, New York (1983-1987).

6. Over my career, I have been appointed to a number of positions including, Chairman of the Young Physicians Committee, Co-Chairman of the Membership Committee for

the Westchester County Medical Society, the Lawrence Hospital Search Committee for Selecting Chief Executive Officer, and the Lawrence Hospital Surgical Planning Committee.

7. I am currently a Fellow in the American Academy of Orthopaedic Surgeons and sit on the Lawrence Hospital Medical Board. I am also a member of the New York State Medical Society, Westchester County Medical Society, and the Lawrence Hospital Physicians Organization. For additional information regarding my professional affiliations, please see my curriculum vitae, a copy of which is attached hereto as Exhibit A.

II. STATEMENT OF OPINION

8. It is my understanding that the United States Food and Drug Administration ("FDA") recently indicated a willingness to permit generic versions of SKELAXIN® to omit bioavailability information from their labeling. Specifically, FDA has stated that generic product sponsors may omit from their labeling the results of clinical studies demonstrating a significant increase in the bioavailability of SKELAXIN® when co-administered with food. Based on my experience as discussed above, my personal experience prescribing SKELAXIN®, and my review of the materials listed in Exhibit B, it is my opinion that the section in the SKELAXIN® labeling reporting the relative bioavailability of metaxalone when taken with and without food (specifically, a significant increase in oral bioavailability of SKELAXIN® when co-administered with food), as demonstrated by clinical studies, is information critical to physicians who prescribe SKELAXIN®. As such, this same information would also be critical to physicians who might prescribe generic versions of SKELAXIN®. This information aids in the safe and effective prescribing and use of SKELAXIN®. In my opinion, the decision of the FDA to

permit the omission of bioavailability information from the labeling of generic versions of SKELAXIN® raises serious safety and efficacy concerns.

A. **The Prescribing Physician's Reliance on Labeling Information**

9. As a prescribing physician, I pay particular attention to all information provided in a drug's labeling. The labeling for any drug product is the single immediate source for determining whether and how that drug is to be dosed and administered. One aspect of drug labeling describes a drug's pharmacokinetics, which information is used by a physician to determine how a patient will process and/or react to the drug. One of the parameters that is used to describe a drug's pharmacokinetics is bioavailability, or the rate and extent at which the drug is absorbed by the body.

10. When prescribing drugs to patients, a physician needs to know conditions that may affect bioavailability. Information concerning such conditions is critical to predicting drug plasma levels, which, in turn, is critical in deciding how a drug should be administered to a specific patient. Not knowing the variables that might affect drug bioavailability can lead to problems with patient safety and/or treatment efficacy.

11. I am familiar with studies that are conducted to ascertain whether and how food affects a drug's bioavailability. Such studies are designed to determine the relative direction and magnitude of changes in a drug's bioavailability when administered with food as compared to when administered without food. Without such studies, the effect of food on bioavailability can be very complex and difficult to predict.

12. Unexpected or unpredictable changes in a drug's bioavailability can lead to complications involving both the treatment of a patient and the patient's overall health. In

particular, when the bioavailability of a dose is more than expected under specific conditions, a potential safety risk can be created for the patient unless the dosage is adjusted accordingly. Moreover, fluctuations in bioavailability can hinder a physician in determining the most effective dose for a particular patient under certain conditions unless sufficient information is provided to characterize those fluctuations.

B. The Prescribing Physician's Reliance on the FDA to Require Clinical Studies and Informative Labeling

13. It is my understanding that it is common for the FDA to require that applicants seeking approvals for their drug products conduct clinical bioavailability studies to demonstrate the rate and extent of absorption of the drugs under fed and fasted conditions in order to ascertain whether there are food effects. It is also my understanding that generic versions of drugs must have the same safe and effective therapeutic profiles in order to be approved by the FDA and that, in many cases, this must be shown by conducting comparative bioequivalence studies showing that branded and generic drugs have the same bioavailability under both fed and fasted conditions.

14. In my opinion, information relating to the bioavailability of a drug product is crucial to a prescribing physician for determining a dosage regimen. I, and other prescribing physicians, rely on the FDA to ensure that clinical studies have been conducted to ensure the safety and efficacy of new drug products as well as generic versions of already approved drug products. Because unexpected changes in the bioavailability of a drug product can cause significant clinical consequences, I rely on the FDA to require studies from which I can elucidate the conditions that may affect bioavailability.

15. I also rely on the FDA to ensure that the results of such studies are provided in the drug labeling. Unexpected changes in the bioavailability of a drug product pose safety and efficacy concerns. If there is information that can be used to determine whether an adjustment in dosage or administration will provide better drug treatment for a patient, a responsible prescribing physician wants to know. In my experience, prescribing physicians rely on the drug labeling, including pharmacokinetic information -- whether it is a brand-name product or a generic version of that product -- as their guide to dosage and administration. To this end, the inclusion (rather than the exclusion) of all available information describing the bioavailability of a drug is critical to me.

C. The Prescribing Physician's Reliance on the Information in the Current SKELAXIN® Labeling

16. As a physician, I regularly prescribe skeletal muscle relaxants, including SKELAXIN® (having metaxalone as the active ingredient) to alleviate skeletal muscle pain. I administer SKELAXIN® to males and females of various ages. I commonly prescribe SKELAXIN® in addition to other drugs or drug regimens for pain management.

17. The SKELAXIN® labeling reports data concerning the absorption and metabolism of the drug in the Clinical Pharmacology section. The data provided in this part of the SKELAXIN® labeling demonstrates that when SKELAXIN® is administered with food, the bioavailability of metaxalone is significantly increased. Based on the SKELAXIN® labeling, it is clear that there is a dramatic increase in the oral bioavailability of metaxalone when the drug is co-administered with food.

18. If the information provided in the current Clinical Pharmacology section of the SKELAXIN® labeling were omitted from either the SKELAXIN® Package Insert or the

Package Insert for generic metaxalone products, I would expect a physician reading that incomplete labeling to conclude either that the bioavailability of metaxalone was unchanged when co-administered with food relative to administration without food or, alternately, that the effects of food on the bioavailability of the drug were unknown. The physician would therefore most likely conclude that it would be unnecessary to adjust the dosage or administration of SKELAXIN® to account for changes in bioavailability due to food-effects. Such an erroneous assumption could lead to sub-optimal dosing strategies and could negatively impact the outcome of drug therapy. Alternately, the physician might consider the possibility that there could be food-effects, but would be unable to make an informed choice of dosage and administration strategies because he or she would have no information about what those effects would be.

19. Because the information on food-effects is provided in the Clinical Pharmacology section of the current SKELAXIN® labeling, I am aware that the bioavailability of SKELAXIN® increases significantly when co-administered with food. As such, I am able to take this information into account and, among other things, adjust the dosage and administration accordingly and select proper dosage regimens for my patients.

20. This bioavailability information is particularly relevant in the clinical setting because it is rare that pain management is achieved by administration of a single drug. In particular, in my experience, I have rarely prescribed SKELAXIN® without also prescribing additional drugs, such as narcotics, barbiturates and anti-inflammatories. Because SKELAXIN® is a central nervous system depressant, in addition to its muscle relaxing effects, SKELAXIN® has potential sedative effects. The SKELAXIN® labeling also indicates that the effects of barbiturates and other CNS depressants may be enhanced by SKELAXIN®. Moreover, the majority of drugs useful for pain management have sedative effects. In view of the potential

drug interactions with SKELAXIN®, understanding that co-administration with food can increase its bioavailability can potentially lead to safer, more effective dosage regimens, with a decrease in the volume and frequency of dosage needed for effectiveness.

D. The Potential Reliance by Physicians on the Similar Information Submitted in the Proposed Labeling

21. I have also reviewed proposed revised labeling for SKELAXIN®. The proposed labeling contains additional analyses of the clinical pharmacology of SKELAXIN®. In particular, additional clinical studies were conducted to determine the effect of age and gender on the bioavailability of SKELAXIN®.

22. Of particular relevance, the results of the studies demonstrate that as age increases, so does bioavailability of SKELAXIN®, but only in the absence of food. In contrast, when co-administered with food, age has little or no effect upon the rate and extent of absorption of SKELAXIN®. The study results therefore demonstrate that age-related variations in the bioavailability of SKELAXIN® can be minimized when SKELAXIN® is co-administered with food.

23. As a physician who prescribes SKELAXIN® to patients over a wide range of ages, this information is critical because the bioavailability of SKELAXIN® varies among age groups in the absence of food. Indeed, I would follow the recommendation to administer SKELAXIN® with food in order to ensure more consistent drug plasma levels.

24. The additional studies submitted for inclusion in the SKELAXIN® labeling also demonstrate that gender has a statistically significant effect on the rate and absorption of

SKELAXIN®. The bioavailability of SKELAXIN® is significantly higher in females than in males.

25. As a prescribing physician who prescribes SKELAXIN® to both male and female patients, this information is important. Based on this information and information about the food-effects on SKELAXIN® I can adjust the dosage and administration accordingly in order to ensure more consistent drug plasma levels.

26. Thus, in view of the results of the studies demonstrating the effect of age and gender on bioavailability and the prescribing physician's necessary reliance on these results, it is even more imperative that the label includes all available information concerning the bioavailability of SKELAXIN®.

CONCLUSION

27. It is my opinion that the labeling for a drug product is the guide for determining whether and how that drug is to be dosed and administered. In addition to information in the "Dosage and Administration" section of a drug label, physicians also rely on other sections of the labeling to provide important information such as conditions that may affect drug bioavailability, which is necessary to consider in choosing, among other things, appropriate doses and in providing appropriate dosing instructions to the patient. As described above, I, and other prescribing physicians, rely on such information to help predict drug plasma levels and help to avoid problems with patient safety and/or treatment efficacy.

28. In particular, based on my review of the current SKELAXIN® label and the proposed labeling, any omission of bioavailability information from labeling for SKELAXIN® or for generic metaxalone products, including the information in the current SKELAXIN®

Package Insert describing the relative bioavailability of metaxalone when taken with and without food, and the age and gender effect information in the proposed SKELAXIN® labeling, is potentially misleading. In the clinical setting, the SKELAXIN® label and its bioavailability information is the single immediate guide to physicians for determining the dosage amount, frequency, and dosing conditions that will provide optimal patient safety and therapeutic efficacy.

29. Pharmacokinetic information describing the relative bioavailability of metaxalone when taken with and without food in the current SKELAXIN® label is important to the safe and effective prescribing and use of the drug for any indication. Similarly, the proposed additional pharmacokinetic information concerning age and gender effects on bioavailability is also important to the safe and effective prescribing and use of the drug. Accordingly, this information should appear in labeling for SKELAXIN® as well as labeling for any generic versions of SKELAXIN® marketed in the future.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

3/17/04
Date

Michael E. Elia, M.D.

EXHIBIT A TO EXHIBIT 7